

REMARKS/ARGUMENTS

The specification has been revised to address various minor informalities, and to delete redundant information from the specification as explained below.

Claims 9 and 11 have been revised to address minor informalities in language without altering the scope of the claims.

Claim 23 has been revised to use alternative language directed to the intended subject matter. No change in claim scope is intended or believed to have occurred.

No new matter has been introduced, and entry of the above amendments is respectfully requested.

Restriction Requirement

Applicants acknowledge the recombination of claims as set forth on pages 2-3 of the Office Action. But Applicants respectfully point out that claims 49 and 50 are directed to subcombinations that are fully within the scope of the combination subject matter encompassed by the claims that have been searched and examined. Therefore, the standards for restriction set forth at MPEP 806.05(c) for situations of combination/subcombination must be met to support the asserted restriction and the withdrawal of claims 49 and 50 from examination.

The applicable standards include the need to demonstrate that “the combination as claimed [the examined claims in the instant case] does not require the particulars of the subcombination as claimed [claims 49 and 50 in the instant case] for patentability”. Applicants respectfully submit that the standards for subcombination/combination situations have not been applied or met in the instant case, and so no proper basis for restriction between the examined claims and claims 49-50 has been presented.

Therefore, Applicants respectfully submit that the withdrawn claims should be searched and examined prior to the issuance of the next Office Communication.

Priority

Applicants acknowledge, but disagree with, the statements on pages 4-6 of the Office Action. Applicants respectfully submit that there has not been sufficient consideration provided to the descriptive support present in the priority document. But given the absence of any rejections based upon cited documents with a disclosure date, Applicants believe that no further discussion of this issue is necessary.

Sequence Compliance

Page 6 of the Office Action presents a requirement for the Appendix in the instant application (on pages 74-187) to comply with the Sequence Rules. Applicants respectfully submit that the Appendix was presented in the application on filing to stand in place of a Sequence Listing. Now that a Sequence Listing is present in the application, the presence of the Appendix constitutes an unnecessary duplication of information found in the Sequence Listing. Therefore, Applicants have deleted the content from pages 74-187 as presented above, and revised the remainder of the application accordingly.

The requirement for sequence compliance is thus believed to be obviated, and so it may be withdrawn.

Specification

An objection to the specification was made based on informalities in three tables. The specification has been revised on pages 31, 39, and 43 to address this issue. This objection is thus believed to be obviated, and so it may be withdrawn.

Claim objections

Claims 9 and 11 were objected to based on a requirement to “spell out” abbreviations. As presented above, claims 9 and 11 have been revised, and this rejection may be properly withdrawn.

Claims 32-38, 42, and 59-60 were objected to as comprising “non-elected subject matter.” Applicants respectfully traverse for the reasons presented above in connection with the

Restriction Requirement. Reconsideration and withdrawal of this objection is respectfully requested.

Claim 36 was objected to as having been presented with the incorrect status identifier. Applicants apologize for that clerical error and thank the Office for examination of the claims without a formal requirement for correction. Given entry of claim 36 in its revised form, Applicants believe that no further correction is needed.

Alleged claim rejections under 35 U.S.C. § 112, second paragraph

Claims 6, 8, 14, 16, 23, 25 and 32-33, along with dependent claims 7, 9-13, 15, 17-22, 24, 26-31, 34-38, 42, and 52-66, were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 6, 8, 14, 16, 23, 25, and 32-33 were rejected based on the alleged indefiniteness of the term “antiestrogen agent”. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of indefiniteness is present. As an initial matter, the term is not to be viewed in a vacuum, but rather considered from the perspective of the skilled artisan in the context of the claim and in light of the specification. Based on this standard, Applicants point out that the context is that of an “antiestrogen agent against breast cancer”. Such agents are known to the skilled artisan familiar with the treatment of breast cancer. Additionally, Applicants point out that while the term is broad, breadth is not indefiniteness. This is clearly shown by the standard set forth at MPEP 2173.04 and by the case decisions cited therein. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Claim 23 was rejected based on the alleged indefiniteness of the term “appropriate treatment”. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of indefiniteness is present. Simply put, the term is broad, but breadth is not indefiniteness as explained above. But to advance prosecution without acquiescence to this rejection, the claim has been revised to include the implicit feature of

treating a patient based on their responsiveness to an antiestrogen agent. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Alleged claim rejections under 35 U.S.C. § 112, first paragraph

Claims 6-38, 42, and 52-66 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an adequate written description. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of an inadequate written description is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

The rejection alleges that sequences “critical or essential to the practice of the invention are not supported by the disclosure.” Applicants respectfully, but strongly, disagree because the instant application contains multiple representative species of HoxB13 and IL17BR gene sequences in the Appendix and Sequence Listing as filed. Additionally, the specification expressly describes the use of any HoxB13 or IL17BR sequences of the corresponding human HoxB13 and IL17BR gene clusters, respectively. Representative sequences from those clusters are presented in Table (i) for IL17BR and Table (iii) for HoxB13, while the specific sequences of these representatives were provided via the Appendix and the Sequence Listing.

Therefore, Applicants respectfully submit that contrary to the instant rejection, there is no improper incorporation by reference of sequence information.

Additionally, Applicants point out the recent Federal Circuit guidance in *Capon v. Eshhar* (76 USPQ2d 1078 (Fed Cir 2005)) which expressly held that there is no need to disclose sequence information that is known in the art. Applicants respectfully submit that the disclosed HoxB13 and IL17BR gene sequences are examples of such known sequences, as shown by the multiple sequences present in each cluster, and there has been no evidence provided to contradict this position. Therefore, no *prima facie* case is present, and this rejection may be properly withdrawn.

Claims 6-38, 42, and 52-66 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an adequate written description. Applicants have

carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of an inadequate written description is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

The basis of this rejection appears to be that more representative species of various components of the claims (such as antiestrogen agents; breast cancer cells; and HoxB13 and IL17BR nucleic acid sequences) are necessary before there is an adequate written description of the invention. Applicants strongly traverse because the skilled person is already apprised of such agents, cells, and sequences. They are all based upon knowledge in the art, including clinical knowledge regarding the treatment of breast cancer and sequence databases. Additionally, and with respect to the alleged need for sequences, the *Capon* decision discussed above holds that there is no need to disclose sequences that are already known in the art.

The statement of the rejection also includes an assertion that the Ma et al. document (published after the filing date of the instant application) fails to support the presence of an adequate written description. Applicants respectfully submit that this assertion is misplaced because the statements quoted by Ma et al. support Applicants position that the claimed subject matter, which is also reported in the Ma et al. document, reflects an advance over knowledge in the art. This is supported by the lack of any rejections alleging the lack of novelty or the lack of non-obviousness.

Therefore, no *prima facie* case is present, and this rejection may be properly withdrawn.

Claims 6-38, 42, and 52-66 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an enabling disclosure. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of non-enablement is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

As an initial consideration in traversing the instant rejection, Applicants point out the well established standard that an application must be taken as presumptively enabling unless there is objective reason to doubt the statements contained therein (see MPEP 2164.04 and the

case decisions cited therein, such as *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). This presumption is present before any “determination of enablement” is to occur under the *In re Wands* factors as cited in the instant rejection. Applicants submit that no objective reason has been provided to doubt the presumption of enablement in the pending claims.

And while the instant rejection alleges that the claims are too broad, that there is inadequate guidance and working examples, unpredictability in the art, and a large amount of experimentation, Applicants point out that the ultimate determination is whether undue experimentation is needed to make and use the claimed invention. It is well settled that the presence of enablement does not mean the lack of experimentation. To the contrary, routine and/or repetitive experimentation is the opposite of undue experimentation and is clearly permitted as evident from the facts of *In re Wands*. Applicants respectfully submit that no more than routine and/or repetitive experimentation is needed to make and use the claimed invention.

Contrary to the instant rejection’s allegation regarding the nature of the invention, the claims do not require “knowledge of a correlation” between HoxB13 and IL17BR. Instead, the instant application provides this correlation as an inventive concept that allows the practice of the method based on this correlation.

The above reflects a fundamental misunderstanding of the claimed subject matter. Additionally, the references to van’t Veer et al., Yamamoto et al., Van Rijnsoever et al., Okuda et al., Wu, Lucentini, and Chen et al. are all non-dispositive because none of them relate to the particular HoxB13 and IL17BR sequences at issue. As for Ma et al., the comments in that document alone are insufficient to support an allegation of undue experimentation because only routine and repetitive experimentation are needed as follow-up to that document. This is demonstrated by multiple documents that recognize the contribution made by Ma et al., and so the instant application. These documents include Jansen et al. (*J. Clin. Oncol.* 2007, 25(6):662-668); Jerevall et al. (*Breast Cancer Res. Treat.* 2007), and Goetz et al. (*Clin Cancer Res.* 2006, 12(7):2080-2087). Copies of which will be provided as soon as practicable.

In light of the foregoing, Applicants respectfully submit that no issue of non-enablement is present and this rejection may be properly withdrawn.

Alleged provisional rejections based on nonstatutory obviousness-type double patenting

Claims 32-37, 42, and 59-60 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of co-pending application no. 11/089,097.

This is a provisional rejection because claim 1 of the co-pending application has not been allowed. Indeed, a review of the public patent application information retrieval (PAIR) entry for this application on September 20, 2007 indicates that those claims have not even been examined. Therefore, no actual case of double patenting is possible, and so this rejection may be held in abeyance until either the claims in the instant application or claim 1 in the copending application are/is passed to issue.

Therefore, Applicants request that the requirement for a Terminal Disclaimer be held in abeyance until the pending claims are otherwise held allowable.

Claims 6-38, 42 and 52-66 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims in co-pending application no. 10/727,100.

As explained above, no actual case of double patenting is possible until claims are allowed, and so this rejection may be held in abeyance until either the claims in the instant application or claims in the copending application are passed to issue.

Therefore, Applicants request that the requirement for a Terminal Disclaimer be held in abeyance until the pending claims are otherwise held allowable.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 10/773,761
Amdt. dated September 20, 2007
Reply to Office Action of June 20, 2007

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 425-681-1833.

Respectfully submitted,

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